Lifestyle and dietary group guidance through mobile application (mHealth), randomised controlled trial – Muutos lautasella

Abstract

Background: Changes in diet and at least 5 % weight loss may prevent or delay several obesity-related chronic diseases, such as type 2 diabetes. Technical tools such as mobile health (mHealth) applications seems to be effective in weight loss interventions. However, there is less evidence of integrated and innovative mobile application-based intervention´s effectiveness in long-term weight loss and quality of life. It is usual that lost weight is typically regained. Little is known about specific factors (e.g. social support, sleep, mood) that can improve success on lifestyle changes. New methods for maintaining weight loss and lifestyle changes are needed.

Aims: The aim is to study mHealth application´s effectiveness and which factors (e.g. social support, sleep, mood) implicates success on lifestyle change and weight loss among overweight and obese adults compared to control group. The aim is also to find out the intervention´s effectiveness to quality of life, long term weight loss, dietary intake and eating behaviours, blood glucose and lipids and can the intervention improve self-efficacy.

Methods: Overweight and obese (BMI 25-40 kg/m²), 50-65 years adults (n=120) will be recruited for 6-month intervention period with 2 years follow up. Participants in the intervention group use a smartphone application to keep visual food journal, share their meals and activities with their peer group members and receive virtual coaching from nutritionist. The intervention is based on cognitive behavioral approach. The control group receives leaflet of healthy eating and weight loss. Main outcome measures are weight change and health related quality of life, assessed with RAND-36 questionnaire. Self-efficacy and habit strength will be assessed with scales. Blood fasting glucose, lipids, weight and waist circumference will be measured. Food intake will be measured on three-day food diary and eating behaviours with Three-Factor Eating Questionnaire R18. Overall interaction with the application will be measured continuously throughout the intervention period. Coach´s activity, user logins, meal photos, likes, comments, exercise entries made in application, sleep, stress level and mood will be analysed.

Significance of results: This study will provide new information about the use of mHealth for long term weight loss and helps to identify the markers for successful lifestyle changes. Intervention is easily scalable, and it can provide new methods to be used in healthcare.

Ravitsemus- ja elintapaohjaus mobiilisovelluksella (mHealth), RCT - Muutos lautasella

Tiivistelmä

Tausta: Ruokavaliomuutoksilla ja vähintään 5 %:n painonpudotuksella voidaan ehkäistä lihavuuteen liittyviä sairauksia, kuten tyypin 2 diabetesta. Painonpudotusinterventioissa sähköiset työkalut, kuten älypuhelinsovellukset (mHealth) ovat osoittautuneet melko tehokkaiksi. Tutkimusnäyttöä tarvitaan kuitenkin lisää monipuolisen ja innovatiivisen mobiilisovelluksen vaikutuksesta pysyvään painonhallintaan ja elämänlaatuun. On tyypillistä, että intervention jälkeen paino nousee takaisin. Lisäksi tarvitaan tietoa, mitkä tekijät (esim. sosiaalinen tuki, uni, mieliala) edistävät painonpudotusta, elintapamuutosten tekemistä ja sitä kautta auttavat pysyvässä painonhallinnassa.

Tavoitteet: Tavoitteena on tutkia mobiilisovelluksen vaikuttavuutta ja löytää tekijöitä (esim. sosiaalinen tuki, uni, mieliala), jotka edistävät elintapamuutoksia ja painonpudotusta ylipainoisilla ja lihavilla aikuisilla verrattuna kontrolliryhmään. Tavoitteena on myös selvittää intervention vaikutusta pysyvään painonhallintaan, elämänlaatuun, ravinnonsaantiin, syömiskäyttäytymiseen, verensokeriin, rasva-arvoihin ja parantaako interventio pystyvyyden tunnetta.

Menetelmät: Ylipainoisia ja lihavia (BMI 25-40 kg / m^2), 50–65-vuotiaita aikuisia (n = 120) rekrytoidaan kuuden kuukauden interventiojaksolle, jonka jälkeen on kahden vuoden seurantajakso. Interventioryhmässä käytetään mobiilisovellusta visuaalisen ruokapäiväkirjan pitämiseen, jaetaan ateriakuvat vertaisryhmän kanssa ja saadaan virtuaalista valmennusta ravitsemusasiantuntijalta. Interventio pohjautuu kognitiivisen käyttäytymisterapian menetelmiin. Kontrolliryhmä saa esitteen terveellisestä ravitsemuksesta. Päätulosmuuttujina ovat painonmuutos ja terveyteen liittyvä elämänlaatu (RAND-36-lomake). Pystyvyyden tunnetta ja tavan vahvuutta arvioidaan asteikolla. Veren glukoosi, lipidit, paino ja vyötärönympärys mitataan. Ruuankäyttöä mitataan kolmen päivän ruokapäiväkirjalla ja syömiskäyttäytymistä TFEQ-R18-lomakkeella. Sovelluksen käyttöä (valmentajan toiminta, vuorovaikutus, ateriakuvat, tykkäykset, kommentit, unen määrä, stressitaso ja mieliala) mitataan ja analysoidaan interventiojakson ajalta.

Mitä uutta tutkimus tuo? Tutkimus tuo uutta tietoa mobiilisovelluksen käytöstä pitkäaikaisessa painonhallinnassa ja auttaa tunnistamaan onnistuneen elämäntapamuutoksen taustalla olevia tekijöitä. Interventio on helposti skaalautuva ja se voi tarjota uusia menetelmiä terveydenhuollon käyttöön.

1. Background

It is widely recognized that the prevalence of obesity and comorbidities such as type 2 diabetes continues to increase worldwide (WHO 2018). In recent years the number of obese adults had increased also in Finland. The latest FinHealth -survey (2017) showed that the number of obese working age adult of men is 26 % and of women 28 %. For comparison in 2011 24 % of working age men and 22 % of women were obese. (Koponen et al 2018). Obesity increases the risk of developing diseases such as cardiovascular disease, type 2 diabetes and certain cancers (WHO 2018). Obesity can also affect self-esteem, mood and increase social isolation (Puhl et al 2009).

Obesity-related diseases can be effectively treated or prevented by weight loss (Tuomilehto et al 2001). This is often enough to have a 5% permanent weight loss. In the Finnish Diabetes Prevention Study (DPS), it was first observed that lifestyle changes can reduce the incidence of type 2 diabetes in half. Healthy lifestyle can also increase the quality of life and independence at old age. Low cardiovascular risk in middle age is associated with lower mortality, morbidity, and better quality of life in old age. To get the full benefit, the identification and treatment of risk factors should take place in the middle age (Strandberg et al 2004).

Lifestyle guidance in groups or individual guidance has so far been the basis of obesity management (Pietiläinen 2015). The guidance is traditionally based on achieving a negative energy balance to reduce weight (Current Care Guidelines, 2013). However, such approach seems to be ineffective in the long term, promoting weight regain, body dissatisfaction, eating disorders and low self-esteem (Sarlio-Lähteenkorva et al. 2000, Bacon et al 2011). Consequently, alternative interventions aimed at long-lasting weight loss are needed.

Technical tools such as mobile health (mHealth) applications can offer personalized, low-cost, evidence-based obesity treatments (Hutchesson et al 2015, Sorgente et al 2017). For example, keeping a visual food journal has been shown to have a more effective effect on behavior than written food diaries (Zepeda et al 2008). Technology can help reduce the burden of self-monitoring and provide quick feedback to increase engagement (Burke et al 2012). Also, research has shown that guidance given in a group is more effective than individual guidance (Paul-Ebhohimhen et al 2009). Peer support from the group has a significant impact on the delivery of life expectancy and self-help (Zhang et al 2016). In addition, weight loss progresses if the mHealth app includes a personal contact from interventionist (Jensen et al 2014).

In the previous mHealth studies the methods have varied to text messages and personal digital assistants (PDA) to smartphone applications (Wang et al 2017). There is less evidence of integrated and innovative smartphone application-based intervention´s effectiveness in long-term weight loss and quality of life. Little is known about factors such as the role of the coach and which specific factors can improve success on weight loss and lifestyle changes on virtual groups.

2. Aims and methods

The aim is to study mHealth application´s effectiveness and which factors (e.g. social support, sleep, mood) implicates success on lifestyle change and weight loss among overweight and obese adults compared to control group. The aim is also to find out the intervention´s effectiveness to quality of life, dietary intake and eating behaviours, blood glucose and lipids and can the intervention improve self-efficacy.

Study design, research questions

In this randomised controlled trial participants will be randomised into intervention and control group. Intervention group participants use a MealLogger-smartphone application to keep visual food journal, self-monitor mood, sleep and stress level, share their meals and physical activities with their peer group members and receive virtual coaching from nutritionist. The nutritionist will provide short feedback to participants approximately in every other week via application and intervention group meets virtually six times in the intervention period using video conferencing software. The meeting is led by the nutritionist. Participants

will be also provided a printed participant handbook, leaflet of healthy eating and weight loss, educational information and tasks via application. The intervention is based on cognitive behavioral approach and it promotes intuitive eating. The use of application varies in intervention period and includes intervals. One intervention group has 15-18 participants. Intervention period lasts 6 months.

The control group participants receive leaflet of healthy eating and weight loss. The leaflet is same as in the intervention group.

Research questions are:

1. Does nutrition and lifestyle coaching via mobile application improve quality of life and promote weight loss for overweight and obese (BMI 25-40 kg/m²) adults (50-65 y) compared to control group?

2. Which specific factors improve succeeding on lifestyle changes and weight loss?

Study sample

The participants (women and men) will be requited from Population Registry Centre by sending letters to potential participants and trough collaborates e.g. societies and primary health care form Helsinki metropolitan area and rural areas of Finland (East and Middle Finland). Flyers, social media, email and newspapers are used to reach the participants.

The inclusion criteria are:

- age 50-65 years old

- weight and height consistent with a body mass index (BMI) between 25-40 kg/m²

- Finnish fluency

- ownership of an iOS or Android smartphone and willingness to use mobile application for 6 months and attend ~~3-~~5 visits at the study centre

The exclusion criteria are:

- cardiovascular event in ≤ 6 months

- a condition or medication that would influence weight (for example weight loss medication or weight loss surgery)

- have had weight loss of 5 kg or more in the past 3 months or intending to participate in another weight loss programme in study period

- profound cognitive, developmental or psychiatric disorders, or psychiatric hospitalization in ≤ 12 months

- insulin-treated diabetes

Participants are randomly assigned to the groups after the baseline measurements. Participants will be randomised to study groups in equal ratios. Randomisation will be stratified by BMI (25.0-29.9 and 30.0-40.0) to ensure group balance. The randomisation sequence will be developed by independent statistician. Participants who live in same residence will be allocated to the same group to avoid contamination between groups. Analyses of primary outcomes will be conducted blinded to group allocation.

3. Outcome measures

Outcome measures are completed at baseline, mid-study (3 month) and 6 months. The follow up will be conducted at 12 month and 2-year post intervention. The same instruments will be used for measurements at each time point. All measured variables and timetable are shown in the table 1.

Primary outcome measures

Main outcome measures are weight change (kg) and health-related quality of life (HRQOL). Weight will be measured in light clothing and without shoes to the nearest 0,1 kilogram using a calibrated scale. Weight loss will also be expressed as percentage weight loss. Also, the BMI is calculated. To calculate the BMI, body height (cm) will be measured to the nearest 0,1 cm using a stadiometer at the baseline visit.

The participants quality of life will be assessed by a RAND-36 questionnaire developed to measure health-related quality of life (Hays 1993). The RAND-36 has been validated in various populations and in the Finnish general population (Aalto et al. 1999). There are health-related questions of eight different dimensions: general health perceptions, physical functioning, emotional well-being, social functioning, energy, bodily pain, role functioning/physical and role functioning/emotional.

Secondary outcome measures

Dietary intake, quality and eating behaviors

Participants will keep written food diary on three days (including two week and one weekend days) at several timepoints. Oral and written instructions will be given to the participants for keeping food diary. The intake of energy, nutrients and food items will be analyzed.

Eating behaviors will be studied by Three-Factor Eating Questionnaire R18 (TFEQ-R18) (Stunkard & Messick 1985). This self-assessment questionnaire is developed to measure cognitive and behavioural components of eating in obese populations.

Waist circumference

Waist circumference (cm) will be measured from the bare skin between the lower coastal border and iliac crest. Two measurements will be taken, with acceptable values within 0,5 cm. If these measurements are not within 0,5 cm, a third measurement will be taken and the average of the two acceptable measures will be reported.

Blood tests

Blood tests will be examined after a 10-12 hour fasting period using a capillary blood sample. Obesity increases the risk of cardiovascular disease (dyslipidemia), type 2 diabetes and fatty liver (WHO 2018, Scheen et al 2002). Fasting blood sugar, Hemoglobin A1c, total cholesterol, HDL and LDL cholesterol, triglycerides, alanine aminotransferase and glutamyl transferase are determined.

Blood test will be taken and analyzed by laboratory service company**,** (Synlab). The blood samples are taken by Synlab´s medical laboratory technologists or nurses. Blood samples are not stored or transferred outside the EU and EEA area.

The research team´s medical doctor will be consulted on abnormal laboratory results and participants will be instructed of the treatment options and locations in health care canters or occupational health services.

Self-efficacy and habit strength

Self-efficacy will be measured by scales (Schwarzer & Renner 2000). Also habit strength will be measured. Self-efficacy has been identified as an important determinant of health behaviour, future health behaviour and health behaviour change (Holloway & Watson 2002). Measurement of habit strength is also important when studied the persistence of lifestyle changes and weight loss.

Focus group interview

Before intervention focus group interviews are conducted to find out experiences on weight loss and weight management. The aim is also to find out expectations, intentions and personal goals towards Muutos lautasella -weight loss intervention. This will help improve the intervention design and, in the future, will promote retention. All sessions will be tape-recorded. The approximately duration of session is 1-1,5 hour. The 15 participants taking part of the interviews will be assigned by investigator. Interviews are conducted in three sessions, five participants per group one researcher acting as the primary moderator and one note-taker. The note-taker's purpose is to watch body language, facial expressions, and group reactions that could not be picked up on the tape recordings.

Engagement and the usage of the application

Both quantitative and qualitative measures will be used to identify and analyse factors that may promote weight loss and lifestyle changes. Overall interaction with the application will be measured continuously throughout the study period by data from the application's usage database. Engagement and usage will be instrumentalized as the number, frequency and pattern of self-monitoring entries made, social support received and given, and the time periods of usage. Quantitative measures include frequency and pattern of the coach´s activity, user logins, meal photos, likes, comments, exercise entries made in application (e.g. steps, type of exercise), sleep, stress and mood.

The comments given by coach and peers in the application will be studied using qualitative methods to find out issues behind the processes of lifestyle change and weight loss.

Demographic characteristics

Sociodemographic data will be collected at the baseline visit. Participants will provide information on their age, sex, education, marital status, medical history, medication, physical activity, sleep and other lifestyle habits.

Table 1. Measured variables and timetable

Variables	0	3 month	6 month	12 month (follow up)	2 years (follow up)
Weight	X	X	X	X	X
Waist circumference	X	X	X	X	X
Quality of life, RAND-36	X	X	X	X	X
Self-efficacy, habit strength	X	X	X	X	X
Fasting glucose	X		X	X	
Blood lipids	X		X	X	
Liver values	X		X	X	
Dietary intake	X	X	X	X	X
TFEQ-R18	X	X	X	X	X
Demographic	X				
Physical activity	X	X	X	X	X
The use of application		X	X		

4. Administration of data and follow up, statistical analysis

During the study, personal participant data (such as contact information, demographic variables and information concerning inclusion) collected will be stored in an administrative database at server, which is secured with a password. Participants will be linked to an ID-number and identifiable information will be kept separate from the study data (collected with the questionnaires). Only the research team will have access to the code that connects the ID number to a person. Personal data will be stored for 15 years and will be destroyed after this time period. Indirectly identifiable information will be substituted with less identifiable variables in the study data set to reduce identification risks: month and year of birth will be changed into age.

Data of the different time points (prior to study baseline, mid-intervention, end of study, follow up and potentially drop-out) will be merged on participant level so that one fully encrypted study data set (without personal information of participants) is created.

The administration of data from the application follows General Data Protection Regulation and MealLogger terms of service.

Statistical analysis

Analyses will follow an intention-to-treat principle. Baseline characteristics will be described (percentages, means ± standard deviations). Engagement and usage of the application will be instrumentalized as the number, frequency and pattern of self-monitoring entries made, social support received and given, and the time periods of usage (percentages, means ± standard deviations). Quantitative measures include frequency and pattern of the coach´s activity, user logins, meal photos, likes, comments, exercise entries made in application (e.g. steps, type of exercise), sleep, stress and mood (percentages, means ± standard deviations). The social interaction and structure between group members will be analyzed. Also, chi-square test for categorical variables and t tests for continuous variables are used.

The primary comparison of primary and secondary outcomes will be between the intervention and control group at 6 months by linear regression approaches. Intervention group differences in weight, quality of life, dietary changes and the use of application will be estimated in an analysis of covariance framework and multivariate logistic regression analysis. Secondary analyses will examine the persistence of lifestyle changes and weight loss of intervention group at 1- and 2-year post intervention.

Most of the data will be presented quantitative, except the analysis for the comments written on application and data from focus group interviews. Qualitative analysis of each focus group session and comments in application will be based on a process of thematic analysis to identify key words or phrases. Categories from each topic will be combined to form themes. Each theme can be compared to rest of the data.

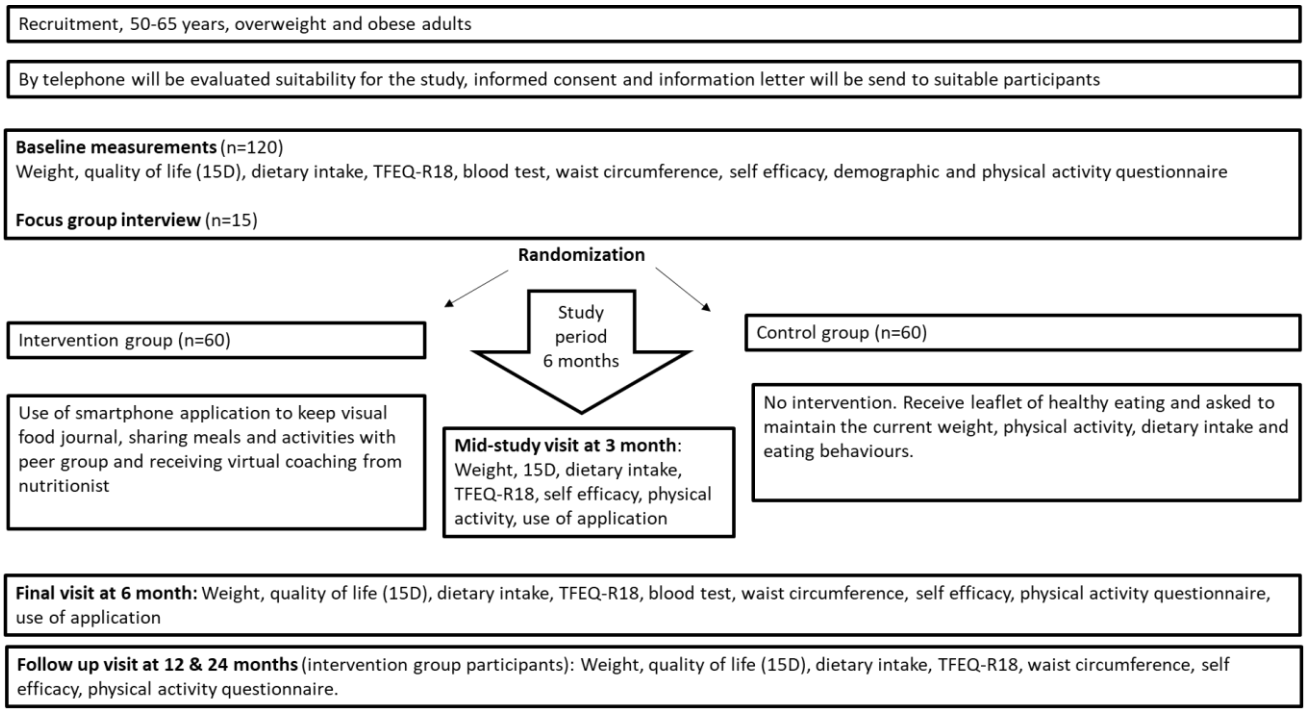
Sample size

Previous studies of eHealth and mHealth interventions showed that mean weight loss at 6 months varied from 0,89 kg to 3,4 kg and to 6,2 kg in intervention groups (McCarroll et al 2017, Grock et al 2017). In DPS study mean weight loss in intervention group was 4,7 kg at 1-year (Eriksson et al 1999). In minimal intervention control groups mean weight loss was 0,72 kg at 6 months (Johns et al 2016). Therefore, we estimate mean weight loss of 4,7 kg at 6-month time point in the intervention group and 0,8 kg mean weight loss in the control group. Primary analysis will compare the intervention group to control group (mean difference 3,9 kg, alpha= 0,05, power 80 %). To provide 80 % power to detect a difference of 3,9 kg between intervention and control group, assuming allocation ratio of 1:1, a total 31 participants per group is required. In previous mHealth studies the dropout rate has varied to 5 % to 55 % with median 20 % (McCarroll et al 2017). In our own pilot groups, the attrition has been on the average 40 %. Therefore and because of the long follow up period, we are recruiting 60 participants per group (total n =120).

5. Ethical aspects

A verbal and written explanation of the study will be given to the participants.
Participants can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a participant from the study for urgent medical reasons. If the baseline measurements show research results that require treatment, the participant will be instructed of the treatment options and locations. The material is handled so that individuals cannot be identified at any time. A statement from the Helsinki University Hospital Ethical Committees is requested for the study. The study will be registered in the Trials Register.

6. Study schedule



Recruitment starts immediately after assent statement from the Helsinki University Hospital Ethical Committees. The intervention period is carried out approximately 10/2019–12/2020 and follow-up by years 2020–2022. Scientific reporting will occur in years 2021–2024.

7. Study group

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8. Results

This study will provide new information about the use of novel mHealth application for long term weight loss and helps to identify the markers for successful lifestyle changes. Intervention is easily scalable, and it can provide new methods to be used in healthcare.

9. Funding

The study is funded from Veikkaus (Funding Centre for Social Welfare and Health Organisations STEA) until year 2020. The annual funding is 115 000 euros. Additional funding for follow up and scientific reporting is sought from Juho Vainio Foundation, Päivikki and Sakari Solhberg Foundation, Yrjö Jahnsson Foundation and The Social Insurance Institution of Finland.

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